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VIA ECF & EMAIL
TIV@stevenslee.com
Hon. Thomas I. Vanaskie (Ret.)
Stevens & Lee
1500 Market St., East Tower, Suite 1800
Philadelphia, PA 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation*, Case No. 1:19-md-02875-RBK (D.N.J.)**

Dear Judge Vanaskie:

Plaintiffs respectfully submit this letter to provide an overview of this litigation.

I. INTRODUCTION & BACKGROUND

A. Overview

This multidistrict litigation ("MDL") involves one of the most expansive prescription pharmaceutical recalls in United States history, concerning three common generic blood pressure medications: valsartan, losartan, and irbesartan. These drugs were contaminated and sold for years with unacceptable levels of carcinogenic nitrosamines. To date, this litigation has focused on valsartan containing drugs ("VCDs").[1] Claims involving the losartan containing drugs

[1] Plaintiffs use the term "valsartan containing drug" or "VCD" to connote that the valsartan products at issue here were *not* the same as Diovan, as required by federal and state law or

("LCDs") and irbesartan containing drugs ("ICDs"), which were filed and coordinated later, have been paced to allow the valsartan claims to proceed first, for reasons discussed *infra* Part V.C.

B. Valsartan & Nitrosamine Contamination

Valsartan is the generic version of the blockbuster brand name hypertension drug Diovan. In the 2000s, attempting to capitalize on the billion-dollar market share for the product, various generic drug manufacturers developed their own generic versions of Diovan (and a related combination product that included valsartan, called Exforge). However, rather than use the same manufacturing process for the critical component of the finished product, the valsartan active pharmaceutical ingredient ("API"), adopted by the brand manufacturer of Diovan and Exforge, the defendant manufacturers in this case made critical process modifications to increase yield and reduce cost. When making these critical modifications, the defendant manufacturers failed to conduct the necessary and required comprehensive risk assessments that manufacturers selling drugs in the United States are required to conduct prior to implementing such critical manufacturing changes. Once they began selling these VCDs in the United States, the defendant manufacturers also disregarded tell-tale signs that there were issues with the valsartan API in their products, failing to properly investigate and analyze any aberrations that became known before, during, and after the manufacturing process, such as unidentified impurities.

The result of these manufacturing decisions led to the formation of N-nitrosodimethylamine ("NDMA"), N-nitrosodiethylamine ("NDEA"), and other nitrosamines in the API of the VCDs manufactured and sold by the manufacturer defendants. The inherent, systemic flaws in the manufacturing and quality assurance practices allowed all or nearly all of

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regulations, due to the nitrosamine contamination and failure to adhere to cGMPs during the manufacturing process. While VCDs may contain the active pharmaceutical ingredient normally found in valsartan, they also contain, e.g., an additional contaminant that distinguishes a VCD from a non-adulterated, properly-made valsartan product.

defendants' VCDs to become contaminated with these undisclosed, dangerous carcinogens.[2] Defendants then proceeded to sell these VCDs to consumers for years in the United States, including the Plaintiffs discussed *infra* at Part I.C.

The nitrosamine contamination created an inherently dangerous pill, which, taken daily, has caused thousands of people to develop cancer to date, and an untold number are at increased risk in the future. The rampant failures to comply with current good manufacturing practices ("cGMPs") resulted in the unacceptable contamination, allowed the contaminated drugs to be sold in the United States for years, and rendered the VCDs adulterated, misbranded, and economically worthless.

Defendants had an obligation to ensure that the VCDs they sold were the generic equivalent, or in layman's terms the "same," in all material respects, as Diovan and Exforge. But their VCDs were not the "same." Defendants' VCDs contained non-FDA approved contaminants that were not present in Diovan or Exforge, let alone approved by the FDA for inclusion in any defendant's VCD (or any other drug, for that matter).

Defendants at each stage of the distribution chain had independent obligations to ensure the products they sold were what they said they were – the generic equivalent of the branded drug. These obligations extended down the stream of commerce, requiring the defendants who sell drugs to make certain they were sourcing VCDs from reputable generic manufacturers, who adhered to at least the minimum, base-line manufacturing and quality assurance practices. But no defendant, be they manufacturer, wholesaler, or retail pharmacy, took adequate steps to detect or guard against the sale of contaminated VCDs to plaintiffs, the foreseeable end-users and end-

[2] NDMA, NDEA, and other nitrosamines are known human carcinogens. These are not typical one-off impurities which should be present in pharmaceutical products and can be controlled. The only practical use for NDMA and other nitrosamines is to induce cancer in laboratory animals for advancement of cancer research.

payors for the VCDs. What is more, the contamination certainly was known or knowable to each defendant. A third-party API customer quickly discovered the contamination upon evaluating ZHP's API samples with an eye to potentially purchasing large quantities for its own use. Once provided with the information, the FDA and similar regulatory bodies abroad acted swiftly and decisively to remove these products from their markets.

Notably, there is no serious dispute that the nitrosamine contamination occurred here. Since the original revelations about contamination became public in July 2018, the FDA has disseminated information identifying which VCDs were subject to recall, and later the contamination levels for those VCDs based on the FDA's own testing and analysis. Indeed, to this day, the FDA maintains a robust, searchable webpage solely dedicated to which VCDs and other sartan drugs have been recalled to date. Many, if not all of the defendants in this action (identified in Part I.D, *infra*) have admitted that their VCDs were contaminated by virtue of their own recall notices, or other statements to the public or government regulatory bodies.

C. The Plaintiffs

There are three parallel master actions proceeding under the same MDL umbrella in this litigation, seeking different types of damages: personal injury, economic loss, and medical monitoring. Individual personal injury plaintiffs assert that their ingestion of VCDs caused them physical injury, the development of cancer. Each personal injury plaintiff has filed an individual, court-approved short-form complaint, that incorporates by reference the Personal Injury Master Complaint. Economic loss plaintiffs include both consumers and third-party payors seeking monetary damages and injunctive relief for their payments for VCDs; their claims and those of the alleged class are reflected in the Economic Loss Master Class Action Complaint. Finally, medical monitoring plaintiffs are consumers seeking monetary and injunctive relief for screening

for cancers they may develop in the future due to ingestion of VCDs; their claims and those of the alleged class are reflected in the Medical Monitoring Master Class Action Complaint.

D. The Defendants

The defendants in this litigation primarily cover entities at four major stages of drug manufacture: (i) API manufacturers, who make the active valsartan ingredient in VCDs; (ii) finished dose manufacturers, who purchase and incorporate the API into the finished formulation, final pill form (e.g., they combined the API with other inactive ingredients, such as preservatives, binding agents, and dyes); (iii) wholesalers, who purchase VCDs from manufacturers and sell them downstream; and (iv) retail pharmacies, who purchase VCDs from manufacturers or wholesalers, and in turn sell and dispense them to patients. Some defendants are vertically integrated and operate at multiple levels. For example, defendant Zhejiang Huahai Pharmaceutical and Mylan make valsartan API and sell it to third-party finished dose manufacturers (such as defendants Teva and Torrent), but also use their own valsartan API to make their own finished dose VCDs. This is also the case for Hetero and Aurobindo. There are some other entities in the supply chain, such as repackagers, but for the most part they have been dismissed without prejudice pursuant to a tolling agreement. *See* 10/3/19 Order (ECF 248). Each defendant's name and role is summarized in plaintiffs' omnibus opposition to the motions to dismiss.

II. MOTIONS TO DISMISS

Judge Kugler initially deferred the filing of motions to dismiss by the defendants. Ultimately though, at the defendants' insistence, Judge Kugler set a briefing schedule in the middle and second half of 2019. To date, Judge Kugler has issued five separate orders on the defendants' motions to dismiss. *See* 12/18/20 Op. & Order (ECF 675, 676); 1/12/21 Op. &

Order (ECF 728, 729); 1/22/21 Op. & Order (ECF 775, 776); 1/29/21 Op. & Order (ECF 818, 819); 2/3/21 Op. & Order (ECF 838, 839). The Court refused to dismiss any claims on the basis of preemption. The only claim the Court dismissed with prejudice was the Magnuson-Moss Warranty Act claim alleged in all three Master Complaints. *See* 1/22/21 Order (ECF 776).

As to the remaining state law claims, the Court dismissed certain claims with leave to amend, but otherwise all three tracks in this litigation (personal injury, economic loss, and medical monitoring) continue to proceed. Plaintiffs intend to file amended Master Complaints once Judge Kugler enters the final motion to dismiss order. Of particular note, in denying motions to dismiss the breach of express warranty claims, Judge Kugler found "that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure." 1/22/21 Order (ECF 775) at 20. "Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for. Further, contaminated drugs do create a present injury because their sale should never have occurred." *Id.*

III. NOTABLE PROCEDURAL ORDERS

The various procedural orders entered by Judge Kugler and Magistrate Judge Schneider include a direct-filing order to allow new cases to be filed directly into this MDL in the District of New Jersey, instead of having to be filed in a different jurisdiction and then transferred here by the JPML. *See* 4/9/19 Order (ECF 76). There is a court-approved short-form complaint for valsartan personal injury cases, *see* 8/20/19 Order (ECF 187), and orders providing that the parties shall use a third-party litigation management system to complete and serve certain

documents such as short-form complaints and fact sheets. *See* 6/19/19 Order (ECF 128); 2/18/20 Order (ECF 376). The Court also entered a Confidentiality and Protective Order (ECF 139), an ESI Protocol (ECF 127), and a Deposition Protocol (ECF 632).

IV. DISCOVERY STATUS

A. Discovery To Date

Prior to his retirement, Magistrate Judge Schneider took an extremely proactive approach to discovery. He held twice monthly conferences with the parties (in-person prior to the COVID-19 pandemic; thereafter telephonic). *See, e.g.*, 4/2/19 Order (ECF 72). Typically, Judge Kugler conducts a case management conference at the end of each month following the discovery conference. With guidance from Judge Kugler, Magistrate Judge Schneider quickly set-out to have the parties engage in "core discovery" to ensure the prompt production of important, non-objectionable documents, such as the manufacturer defendants' communications with the FDA about NDMA. *See, e.g.*, 6/17/19 Order (ECF 120).

Next, focusing on the manufacturer defendants first, Magistrate Judge Schneider held extensive briefing and oral argument on "macro discovery" issues that cut across the plaintiffs' document requests to all manufacturer defendants. *See, e.g.*, 10/18/19 Order (ECF 273); 10/22/19 Order (ECF 280). In quick succession, Magistrate Judge Schneider established the general temporal, geographic, and subject-matter parameters of discovery aimed at the manufacturer defendants. *See, e.g.*, 10/22/19 Order (ECF 280), 11/25/19 Order (ECF 303). He also approved custodian lists for each manufacturer defendant. *See* 12/13/19 Order (ECF 318). Finally, he entered the court-approved document requests for which each manufacturer defendant was to produce documents. *See* 12/23/19 Order (ECF 328). He did the same with the plaintiff

fact sheets that each type of plaintiff (personal injury, economic loss, or medical monitoring) had to answer. *See* 10/3/19 Order (ECF 249); 10/28/19 Order (ECF 283).

Economic loss and medical monitoring named plaintiffs produced their fact sheets and any documents in early 2020. Personal injury plaintiffs have been completing fact sheets on a rolling basis, based on court deadlines for when such fact sheets must be submitted. Subsequently, Magistrate Judge Schneider approved the defendant fact sheets to be completed by each tier of defendant, and deadlines for same. *See* 8/6/20 (ECF 546).

The manufacturer defendants, despite being ordered to substantially complete their document productions by November 30, 2020, failed to do so. For the better part of 2020, plaintiffs vigorously disputed the pace of the manufacturers' document productions, and Judge Schneider chose to accord the manufacturers the benefit of the doubt. In the past week, the manufacturer defendants requested an extension of all discovery deadlines so they would have more time to produce documents that were supposed to have been produced months ago, prior to the wave of corporate depositions that is approaching.

Discovery of the wholesaler and retail pharmacy defendants has been incredibly narrowed to date. After months of negotiation, Magistrate Judge Schneider set a briefing schedule and oral argument on Plaintiffs' written discovery to these two tiers of defendants, and ultimately entered the court-approved document requests in July 2020. *See* 7/9/20 Order (ECF 509). Notably, this discovery was largely focused on data and heavily redacted exemplar documents, and did not include any custodial discovery. Plaintiffs served draft supplemental document requests and deposition notices on these defendants in December 2020. Plaintiffs await a substantive redline or counterproposal from either group of defendants.

Currently, after lengthy negotiation and prior direct intervention by Magistrate Judge Schneider, plaintiffs are in the process of taking or scheduling depositions of manufacturer defendants' witnesses. Since mid-January, defendants have been deposing economic loss and medical monitoring proposed class representative plaintiffs.

B. Anticipated Discovery In Coming Months

Under the revised scheduling order recently entered that extended all case deadlines by sixty days, *see* 2/4/21 Order (ECF 843), plaintiffs expect to complete "phase I" discovery by June 1, 2021. This phase includes all depositions of manufacturer defendants' witnesses, all depositions of named economic loss and medical monitoring plaintiffs, and depositions of bellwether personal injury plaintiffs. *See* 1/11/21 Order (ECF 726). Thereafter, the schedule provides for the parties to exchange general causation expert reports and conduct expert depositions, and to file Daubert motions. The parties are to complete "phase II" discovery by October 2, 2021, which includes completion of (i) further discovery of wholesaler and retail pharmacy defendants, (ii) third-party discovery, (iii) depositions of any new named plaintiffs added by amendment to the class actions, (iv) and depositions of the balance of any bellwether personal injury plaintiffs. By November 3, 2021, plaintiffs will be filing a motion for class certification and class expert reports.

V. MISCELLANEOUS

A. Numbers of Valsartan Personal Injury Plaintiffs

Over 600 individual personal injury cases have been filed by valsartan plaintiffs.

B. Bellwether Report

In January 2021, the parties submitted to the Court a slate of 28 bellwether personal injury plaintiffs – two jointly chosen by both sides, 13 chosen by plaintiffs, and 13 chosen by defendants.

C. Losartan and Irbesartan

This MDL originally encompassed claims involving valsartan only. The JPML expanded this MDL to include losartan and irbesartan claims on December 18, 2019. *See* ECF 325. At that time, the parties had already engaged in extensive negotiations and argument about valsartan-related document requests and custodians. To avoid delay, Judge Kugler and Magistrate Judge Schneider directed that litigation of the valsartan claims should proceed apace, with the losartan and irbesartan claims to follow. On December 18, 2020, plaintiffs filed master complaints for losartan and irbesartan, which largely mirrored the three tracks of matters (i.e., personal injury, economic loss, and medical monitoring) for valsartan. *See* ECF 679, 680, 682, 683. The parties submitted agreed-upon short-form complaints and plaintiff fact sheets for losartan and irbesartan personal injury cases on January 29, 2021.

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We hope Your Honor finds this overview helpful, and we will be prepared to answer any questions at the next telephonic case management conference.

Respectfully,

ADAM M. SLATER